SEP - 2 1999

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

J. Trevor Lumb
Pfizer Inc.
Patent Department
235 East 42nd Street
New York, NY 10017-5755

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,264,500

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,264,500, which claims the animal drug product RIMADYL, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be three years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of three years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of October 13, 1998 (63 Fed. Reg. 54716). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \tfrac{1}{2}\,(\text{Testing Phase}) + \text{Approval Phase} \\ &= \tfrac{1}{2}\,(5{,}910 - 911) + 662 \\ &= 3162 \text{ days} \end{aligned}$$

Since the regulatory review period began October 30, 1978, before the patent issued (April 28, 1981), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From October 30, 1978 to April 28, 1981 is 911 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The three year limitation of 35 U.S.C. § 156(g)(6)(C) applies in the present situation, however, because the patent was issued and an action described in 35 U.S.C. § 156(g)(6)(B) was taken before the date of enactment of 35 U.S.C. § 156 (November 16, 1988, see 35 U.S.C. § 156(f)(8)). Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed three years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for three years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,264,500
Granted:	April 28, 1981
Original Expiration Date:	February 28, 2000
Applicant:	Willy Zwahlen
Owner of Record:	Pfizer Inc.
Title:	Process of Making 6-Chloro-α-Methyl-Carbazole-2-Acetic Acid
Classification:	260/315
Product Trade Name:	RIMADYL (carprofen)
Term Extended:	Three years
Expiration Date of Extension:	February 28, 2003

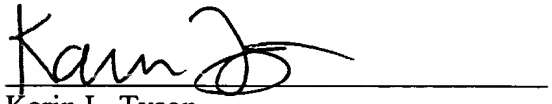
Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

RE: RIMADYL
FDA Docket No.: 97E-0012